

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419

THIS DOCUMENT RELATES TO:

Dkt. No. 1:13-md-2419 (RWZ)

All Suits Naming St. Thomas Outpatient
Neurosurgical Center

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM IN OPPOSITION TO
TENNESSEE CLINIC DEFENDANTS' MOTION TO COMPEL COMPLETION OF
THE DEPOSITION OF DAVID A. KESSLER, M.D.**

The Federal Rules of Civil Procedure set forth a seven-hour limit for depositions, and additional time is not allowed without good cause shown. Counsel are expected to make strategic choices to make the most of those seven hours; inefficient use of deposition time is not good cause for requesting more time. Here, Defendants' counsel used his seven hours inefficiently, choosing to fill the time with questions on marginal topics, playing hide-the-ball with documentary evidence, and larding the record with aggressive, argumentative, and sarcastic commentary, instead of inquiring about the opinions Dr. Kessler offered in his report. This was counsel's strategic choice in how to use his allotted time, and his inefficiency does not constitute good cause for getting more time.¹

David Kessler, M.D., is the former Commissioner of the United States Food and Drug Administration, serving in that role for seven years, under two presidents of different parties. Dr. Kessler is an experienced witness who has testified many times before Congressional

¹ This is particularly true given that Plaintiffs' counsel offered Defendants' counsel an additional 30 minutes past the seven-hour mark on the day of the deposition, which Defendants' counsel refused, instead certain that he would convince this Court to give him additional time. Kessler Dep. Tr. 282:8-282:13, 326:9-11. (All pages of the transcript of Dr. Kessler's March 4, 2016, deposition that are cited in this brief are collected in the attached Exhibit A.)

committees, and in trials of litigated matters; he has been deposed numerous times as an expert witness in federal MDLs and individual cases. No judge has ever sanctioned Dr. Kessler, and, on the contrary, he has provided invaluable insights to judges and juries regarding the regulatory process. No opposition counsel has ever found reason to request, let alone get, additional time to depose Dr. Kessler beyond the standard seven hours permitted by the Rule.² The transcript shows that Dr. Kessler maintained a careful and respectful demeanor during his deposition, which is particularly commendable in light of Defendants' counsel's argumentative, badgering questions, repeated interruptions of Dr. Kessler's answers, and insulting comments made towards him. Nor did Plaintiffs' counsel ever sink to Defendants' counsel's level; the transcript makes clear the only breach of civility here was on the part of Defendants' counsel. Defendants' motion should be denied.

I. DEFENDANTS HAVE NOT SHOWN GOOD CAUSE FOR ADDITIONAL DEPOSITION TIME.

The party moving for additional time for deposition bears the burden of proving the need for time beyond the seven-hour limit set by Fed. R. Civ. P. 30. The Committee Notes on the 2000 Amendments to Rule 30 state: "The party seeking a court order to extend the examination [beyond the presumptive seven-hour limit] is expected to show good cause to justify such an order." Defendants have not met that burden.

As one federal court explained the background and purpose of this aspect of Rule 30:

[T]he court should begin with the presumption that the seven-hour limit was carefully chosen and that exceptions to that limit should be the exception and not the rule. Automatic extensions eviscerate the rule. Moreover, the seven-hour limit

² Defendants' motion is little more than harassment of Dr. Kessler, consistent with their recent issuance of three subpoenas on third parties in an attempt to obtain documents concerning Dr. Kessler's prior employment that have nothing to do with the issues in this case. Plaintiffs have moved to quash those subpoenas. [Dkt. 2815]. While Defendants may be concerned (and understandably so) with the effect of Dr. Kessler's opinions on their theory of the case, that is no justification for Defendants' campaign of harassment against Dr. Kessler.

encourages efficiency; it has been said that a writer's best friends are a deadline and a page limitation. The same may be said of lawyers conducting depositions.³

The *Roberson* court made several criticisms of the inefficiencies and misuse of time by deposing counsel, such as spending nearly the entire deposition on the plaintiff's education and "a painstaking review of documents listed in Plaintiff's initial disclosure. Indeed, the deposition ended without any questions specifically directed to the Plaintiff's allegations."⁴

"In every deposition, choices have to be made about the subject matter to be covered" – this is especially so in complex cases, where "[t]he 7-hour rule necessitates ... that almost all depositions will be under-inclusive."⁵ The examiner therefore must be selective and carefully decide how to apportion his time – and once he has, he is bound by the tactical decision he made as to what to cover.⁶

Here, Defendants' counsel⁷ made the strategic decision to use his time as follows:

- **Asking questions about marginal and beyond-scope topics**

In the entire seven-and-a-half hours on the record,⁸ Defendants' counsel did not ask a single question about the opinions offered in Dr. Kessler's Rule 26 expert report. Instead, counsel chose to spend his time questioning Dr. Kessler about a report he offered in a different,

³ *Roberson v. Bair*, 242 F.R.D. 130, 138-39 (D.D.C. 2007) (emphasis added). The decision in *Roberson* permitted additional deposition time only on the grounds that the Plaintiff had failed to produce documents that had been requested previously. *Id.* at 139. That basis for decision is absent here.

⁴ *Id.* at 138-9.

⁵ *In re Sulfuric Acid Antitrust Litig.*, 230 F.R.D. 527, 532 (N.D. Ill. 2005).

⁶ *Id.*

⁷ Defendants' counsel C.J. Gideon conducted Dr. Kessler's deposition; also present was his colleague, attorney Kaycee Weeter (who is an attorney, notwithstanding that Gideon referred to her as his "assistant" during the deposition, Kessler Dep. Tr. 47:19).

⁸ The total time on the record was seven hours and 29 minutes. As the seven-hour mark neared, Plaintiffs' counsel offered Defendants' counsel an additional 30 minutes over the seven hours to allow him to complete the deposition that day. Defendants' counsel rejected that offer, instead counting on coming to this Court to get even more time. Nevertheless, in the spirit of cooperation, Plaintiffs' counsel allowed Defendants' counsel to go over the seven-hour mark with his examination. Kessler Dep. Tr. 326:9-18.

non-analogous case.⁹ In fact, from the beginning of his examination until the lunch break, i.e., approximately half the deposition, Defendants' counsel introduced only a single exhibit relating to the present case.¹⁰ Counsel also chose to spend almost 30 minutes to ask the witness about 21 different cases in which he had given prior testimony at deposition or trial.¹¹ None of those 21 cases concerned compounded drugs, and counsel certainly could have learned who the parties were and what claims were made in those cases were from sources other than Dr. Kessler.¹² In fact, Defendants' counsel repeatedly asked Dr. Kessler for publicly available information that there was no reason Dr. Kessler should know off-hand, and for which no purpose was served by having Dr. Kessler provide (or look up and read into the record) during his deposition.¹³ Counsel also chose to spend his time asking questions about topics outside the scope of Dr. Kessler's report,¹⁴ as well as questions outside Dr. Kessler's areas of expertise.¹⁵ And counsel wasted time

⁹ Kessler Dep. Tr. 158:3-160:16 (questioning Dr. Kessler on his report in the Risperdal MDL, which involved a pharmaceutical company operating under the Food, Drug and Cosmetic Act, not a compounding pharmacy like NECC here).

¹⁰ Exhibit 1247.

¹¹ Kessler Dep. Tr. 110:4-131:19.

¹² To the extent Defendants' counsel sought to establish a tendency to testify for one side or the other in litigation, or with particular counsel, those could have been established in far fewer questions and far shorter time.

¹³ *See, e.g.*, Kessler Dep. Tr. 89:22-90:8 ("Q: I'm not interested in this cellular action, but in what circumstances would a physician use preservative-free hyaluronidase?

A: So I would want to look at the label for hyaluronidase. If you have it, give it to me. And the way we would determine that is look at the label for hyaluronidase and see what it would be indicated for. Again, I don't carry it in my head.

Q: Don't know?

A: I'd want to see what -- it's very easy to get the answer. We'd look at a label and see what the indications for use would be.")

¹⁴ *See, e.g.*, Kessler Dep. Tr. 88:16-89:5 ("Q: How does a class 10 differ from an ISO 5 or an ISO 7 microenvironment?

A: Happy to look that up.

Q: Don't know without looking?

A: Again, I'd be happy -- those things are easy to answer your question. Again, happy to do that right now if you would like me to.

Q: What I'm interested in is whether you know without being prompted by looking at something else.

A: Sir, I'm here as an expert. And again, if you look at my report, I don't go into this. You are asking me questions that are beyond my report. Happy to give you the answers, but in order to do that as an expert, I'd want to make sure. I'm not going to do stuff off the top of my head.")

¹⁵ *See, e.g.*, Kessler Dep. Tr. 252:20-253:7 (questions on topics of infectious disease, on which Dr. Kessler does not purport to be an expert).

asking the witness about the circumstances of his departure from prior employment at FDA and UCSF¹⁶ – issues that are irrelevant to Dr. Kessler’s qualifications and opinions.

- **Misusing or withholding documentary evidence**

Defendants’ counsel misused document excerpts repeatedly, wasting time not only by the misleading examination, but also by necessitating the introduction of additional evidence for completeness pursuant to Fed. R. Evid. 106. For example, in support of its litigation position that FDA did not stop NECC from making or selling its products, Defendants’ counsel insinuated that FDA had failed to investigate an outbreak of *klebsiella* pneumonia in 2008, purportedly associated with NECC’s product. In fact, the complete documents showed that FDA did investigate, that the contamination was found in a product made by a different company, and that “it looks like they ruled out that the problem was from NECC.”¹⁷

In another example, Defendants’ counsel misleadingly used a federal statute, 21 U.S.C. 396, which by its express language is applicable only to medical devices in an attempt to get an admission from Dr. Kessler about drugs; when Dr. Kessler pointed out the explicit inapplicability of the regulation to drugs, Defendants’ counsel snidely (and incorrectly) suggested that was just Dr. Kessler’s “interpretation” of the statute.¹⁸

¹⁶ Kessler Dep. Tr. 71:4-77:6, 64:25-70:3.

¹⁷ Kessler Dep. Tr. 316:20-327:20.

¹⁸ Kessler Dep. Tr. 140:8-141:20 (“Q: This is Exhibit No. 1249. You are familiar with that ... provision of the United States Code, are you not? ... Doesn’t this recite the fact that nothing about the law pertinent to the Food and Drug Administration has any impact on the prerogative, the discretion, of a healthcare practitioner to prescribe or use a drug or device?

A: No, that’s not ... That’s not what that states.

Q: What does this state then, Dr. Kessler?

A: So this applies, as I read this, only to devices.

Q: Okay. Have you ever researched that issue?

A: I’ve written extensively on the issue of off-label promotion, and I implemented the law when I was FDA commissioner. But this has nothing -- you see the word drug here? You handed me that saying that was drugs.

Q: Right.

A: Do you see anything about drugs there?

Q: I’ve gotten your interpretation.

A: No, no, no. ... There’s no interpretation. ... doesn’t say the word drug there, it says device.”).

In another example, Defendants' counsel wasted time attempting to gain a concession about a document that was contradicted by the very same document. In particular, Defendants' counsel asked, "[n]ow, where is there any statement on page 3 of the document that I handed to you, that exhibit that has methylprednisolone acetate at the top, where it says that this can only be dispensed with a patient-specific prescription?"¹⁹ To correct the misleading impression Defendants' counsel tried to create, Plaintiffs' counsel was obliged to read from page 9 of that document, for completeness: "*Product is dispensed by patient-specific prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or facility.*"²⁰ Such examples of misused excerpts that were directly contradicted by the documentary evidence can only be explained by either counsel's intent to mislead the witness or his lack of familiarity with the documents. In either case, the questioning was improper, and the wasted time is attributable to Defendants' counsel's own conduct.

- **Cluttering the record with argumentative and insulting commentary**

Throughout the deposition, Defendants' counsel wasted time on the record asking aggressive, badgering questions, interrupting Dr. Kessler as he tried to answer counsel's questions, and interposing argumentative and sarcastic commentary. For example, Defendants' counsel repeatedly mocked Dr. Kessler for asking to review documents before answering questions based on those documents,²¹ despite the fact that it is perfectly acceptable for an expert witness to request to view the documents he is being asked to opine about. Defendants' counsel

¹⁹ Kessler Dep. Tr. 87:6-10; repeated four times at pages 90-91.

²⁰ Kessler Dep. Tr. 94: 7-13 (emphasis added).

²¹ Kessler Dep. Tr. 321:4-325:3 ("Q: Doesn't this make it clear, didn't FDA know that NECC was selling product that was not being used for specific patients? ... And not being subject to patient-specific prescriptions? [Objection.] A: And can I see my documents that I requested, please, if you can help me? [Witness had already requested the underlying documents twice before during this line of questioning.] ...

Q: I'm going to give Dr. Kessler the opportunity to explain why you need the documents. And if you can tell us why we should spend time on it we'll do it for you. But just to request the documents to talk about them isn't really pertinent.")

consistently used an aggressive, argumentative tone and interrupted Dr. Kessler as he attempted to answer counsel's questions. To give just one representative example:

Q: And when did it first become false? When did the representations by NECC about getting patient-specific prescriptions first, to your knowledge, become just an utter lie. [Objection.]

A: So on -- based on the--

Q: The question is when. [Objection.]

A: I understand exactly. ... So based on the record that I have seen...

Q: I'm directing it to you as the witness, not a record somebody else has seen. So that's implicit. [Objection.]

Q: When? When did their representations about receiving patient-specific prescriptions become an utter lie? [Objection.]

A: So the record that I have seen --

Q: Okay. The record you've seen. We've got that.

A: But -- but -- [Objection.]

A: Hold on. I -- what I'm trying to help you get -- I mean, because the record --

Q: Doctor, you are not helping anybody because you are --

A: I'm trying to answer your question.

Q: -- you are not answering anything."²²

Defendants' counsel's nasty tone and snide commentary only worsened as he became increasingly frustrated that he could not get Dr. Kessler to agree with his misleading and reductive statements. At one point, he prefaced a question to Dr. Kessler, "So from the perspective of this *self-proclaimed expert* in drug regulation..."²³ -- this to an individual who held the highest position in the United States with regard to drug regulation for seven years, and whose expertise on that very subject matter has been repeatedly validated by numerous federal court judges. Indeed, even the United States Supreme Court has cited Dr. Kessler's authoritative work in the field, with approval.²⁴ Plaintiffs submit that this insult was not an isolated or accidental slight, but instead was part and parcel of Defendants' counsel's argumentative and sarcastic approach, in evidence throughout the day.

²² Kessler Dep. Tr. 211:18-213:7.

²³ Kessler Dep. Tr. 262:6-262:8 (emphasis added).

²⁴ See *Wyeth v. Levine*, 555 U.S. 555 at 579, n.12 (2009).

In sum, Defendants' counsel chose to address marginal topics instead of exploring Dr. Kessler's opinions offered in his report, wasted time trying to play "gotcha" by misusing and withholding documentary evidence (often requiring supplementation for completeness under Fed. R. Evid. 106), and peppered the proceedings with aggressive, insulting interruptions and commentary. Defendants' counsel is responsible for those choices, and no "exceptional circumstances" can be found to justify additional deposition time here. While he may now regret them, Defendants' counsel is bound by his decisions on how to use his seven hours.

II. DEFENDANTS' COLLECTION OF OUT-OF-CONTEXT EXCERPTS DOES NOT SHOW ANY EVASION OR IMPROPER RESPONSES BY DR. KESSLER.

The majority of Defendants' brief consists of a series of deposition excerpts taken out of context that do not support their claim of evasive responses. What Defendants' examples do illustrate is how improper, poor, and at times unintelligible Defendants' counsel's questions were throughout the deposition. For example, one such unintelligible question that Defendants rely on in their motion was: "What is the definition of a manufacturer to making large volumes of drugs?"²⁵ In the face of such questions, Dr. Kessler did his best to answer forthrightly and accurately.

First, not a single one of the "Top Ten" asked Dr. Kessler anything about his Rule 26 expert report or the opinions expressed therein. Accordingly, Dr. Kessler was obliged to respond to the best of his ability based on the records he had seen. For example, in Defendants' excerpt #1, counsel asked whether the witness "knows" that a cease and desist order to NECC was not sent by FDA to the Massachusetts Board of Pharmacy.²⁶ The excerpt omits that Dr. Kessler had answered three preceding questions succinctly and briefly, based on what he actually knew. The question that Defendants excerpted for their motion, however, asked for knowledge that Dr.

²⁵ See, e.g., Defs' Mem. at 8 [Dkt. 2766] (quoting Kessler Dep. Tr. 196:6-198:1).

²⁶ Defs' Mem. at 4.

Kessler did not have, so in his response, he described a document that he recalled on the subject: “I have the testimony, let me get it.”²⁷ Defendants’ brief omits that Defendants’ counsel then told the witness, “You are free to do that if you wish,”²⁸ thereby inviting Dr. Kessler to read from the testimony – the very response of which Defendants now complain. Defendants’ excerpt also omits Dr. Kessler’s comment, after reading from the testimony: “That’s the extent of my knowledge.”²⁹

Similarly, in Defendants’ excerpt #9, Defendants refer to a line of questioning regarding statements made by NECC to FDA and whether FDA was “entitled to rely” on those representations. Again, this topic was not covered in Dr. Kessler’s report, requiring him to respond based on his general knowledge. The excerpt also leaves out Dr. Kessler’s explicit reference, a moment later, to an applicable statute, 18 U.S.C. 1001, regarding “a statement to a federal official,” and Dr. Kessler’s definitive answer: “Federal officials are allowed to rely on statements made to them. Of course you are.”³⁰

Without rehashing and refuting each of Defendants’ “Top Ten,” it is clear that Dr. Kessler did his best to provide responsive answers to poorly worded questions that ranged far from the opinions expressed and the facts relied on in his report, and that the time taken for such responses was appropriate, given the circumstances.

²⁷ Kessler Dep. Tr. 266:15-19 (referring to the testimony of FDA and State witnesses at a hearing).

²⁸ Kessler Dep. Tr. 266:20.

²⁹ Defendants’ Memorandum also omits Defendants’ counsel’s argumentative follow-up and interruption of the witness. Kessler Dep. Tr. 269:5-269:11 (“Dr. Kessler: That’s -- again, *this testimony is the extent of my knowledge*. Q. So how does that answer my question then?

A. It—

Q. It doesn’t.

A. It tells—well, she was asked about those questions. *This is the record that I have.*”) (emphasis added).

³⁰ Kessler Dep. Tr. 205:16-17.

III. SANCTIONS ARE UNWARRANTED HERE.

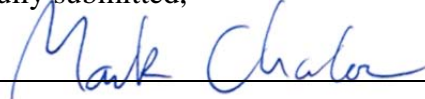
It is ironic that Defendants' counsel argues that Plaintiffs' counsel should somehow be sanctioned for their conduct at the deposition. To the contrary, Plaintiffs' counsel were civil throughout the deposition and no sanctions are warranted. Defendants' reliance on *GMAC Bank v. HTFC Corp.* is misplaced, and offers no support for the claim that Plaintiffs' counsel here acted improperly. In *GMAC*, the court cited the "spectacular failure of the deposition process," due to the "uncivil conduct of the witness," including repeated insults and expletives directed at the examining attorney (73 separate uses of f*** during the deposition); "repeatedly interrupting counsel;" "proudly express[ing] his intent to frustrate his examination;" "storming out of the deposition;" and the defending attorney's failure to admonish the client to curb such outlandish behavior.³¹ The transcript in this case shows no improprieties by Plaintiffs' counsel whatsoever and a witness who remained calm and unflappable throughout, notwithstanding Defendants' counsel's insults and argumentative style. Despite remarking on the day that Plaintiffs' counsel were "[v]ery gracious" during the deposition, Defendants' counsel now claims that Plaintiffs' counsel were so far from "gracious" that they should be sanctioned.³² That argument is without merit.

IV. CONCLUSION

For the reasons stated above, Defendants' motion should be denied in its entirety.

Dated: April 22, 2016

Respectfully submitted,



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³¹ 248 F.R.D 182, 184-191 (E.D. Pa. 2008).

³² Kessler Dep. Tr. 325:8-326:8.

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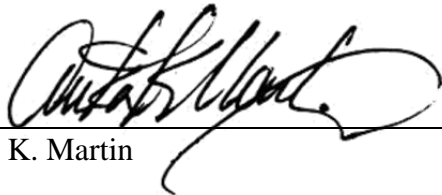
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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Annika K. Martin, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: April 22, 2016



Annika K. Martin